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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RAGHU, GANAPATHIRAM	
ART UNIT	**PAPER NUMBER**
1652	

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10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/802,034	PATEL ET AL.	
	Examiner	Art Unit	
	Ganapathirama Raghu	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *5,39-51 and 53-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *5,39-51 and 53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Application Status

In response to the Office Action mailed on 02/21/2007, applicants' filed a response and amendment, received on 08/21/2007. Said amendment, amended claims 5, 39-42,47, 50, 51 and 53-56, canceled claim 52. Thus claims 5, 39-51 and 53-58 are pending and are now under consideration.

Objections and rejections not reiterated from previous action are hereby withdrawn.

Withdrawn-Claim Rejections: 35 USC § 112-Second Paragraph

Previous rejections of claims 50 and 53-58 under 35 U.S.C. 112, second paragraph, is withdrawn following amendments to claims.

Withdrawn-Claim Rejections: 35 USC § 112-First paragraph

Previous rejections of claims 5 and 39-51 and 53-58 under 35 U.S.C. 112, first paragraph, for enablement and written description is withdrawn following amendments to claims.

Specification Objections

The disclosure is objected to because of the following informalities:

1) Examiner notes that there is a large amount of blank space on page 23.

2) The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 5, 39 and 50 are objected to, due to the following informality: Claims 5, 39 and 50 recite the phrase "...said gene product of *gumB*, and said gene product of *gumC*....". The said phrase is superfluous and extraneous words. Appropriate correction is required.

New-Claim Rejections 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 39 (40-49 depending therefrom) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5 and 39 are not clear and confusing. It is not clear to the examiner how does increasing the amount of a gene product produce a xanthan composition. Clarification is required.

Claims 5, 39 (40-49 depending therefrom) and 50 (51 and 53-58 depending therefrom) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 2 recites the phrase "...*Xanthomonas campestris* (XWCM1/pBBR5BC)". It is not clear to the examiner as to what the phrase "...*Xanthomonas campestris* (XWCM1/pBBR5BC)" means in the context of the above claims, is this synonymous with "a specific strain of *Xanthomonas campestris*" or does it include any *Xanthomonas campestris* including mutants thereof. Clarification is required.

Claims 5, 39 (40-49 depending therefrom) and 50 (51 and 53-58 depending therefrom) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention. Claims 5, 39 (40-49 depending therefrom) and 50 (51 and 53-58 depending therefrom) recite the phrase "...*Xanthomonas campestris* (XWCM1/pBBR5BC)". It is confusing; whether what is within the parenthesis "(XWCM1/pBBR5BC)" is a limitation of the claim or merely exemplary? Clarification is required.

New-Claim Rejections: 35 USC § 112-First Paragraph

Amendments to claims have necessitated the new rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 5 and 39-51 and 53-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 5, 39-42, 46, 47 and 50-56 recite plasmid pBBR5BC comprised in specific strain of *Xanthomonas campestris* XWCM1.

It is apparent that plasmid pBBR5BC comprised in specific strain of *Xanthomonas campestris* is required to practice the claimed invention. As such the biological material must be readily available or obtainable by a repeatable method set forth in the specification, or otherwise readily available to the public. If it is not so obtainable or available, the requirements of 35 USC112, first paragraph, may be satisfied by a deposit of the plasmid pBBR5BC comprised in specific strain of *Xanthomonas campestris*. The claimed plasmid sequences are not fully

disclosed, nor have all sequences derived for their construction and the specific strain been shown publicly available. If a deposit is made under the terms of Budapest Treaty, then a statement, affidavit or declaration by applicants, or a statement by an attorney of record over his/her signature and registration number, or someone empowered to make such a statement, stating that the invention will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If a deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809 and MPEP 2402-2411.05, applicant may provide assurance of compliance by statement, affidavit or declaration, or by someone empowered to make same, or by a statement by an attorney of record over his /her signature and registration number showing that:

(a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting the patent;

(c) the deposit will be maintained in public depository for a period of 30 years, or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (se 37 CFR 1.807); and the deposit will be replaced if it should ever become inviable.

Maintained-Claim Rejections 35 USC § 103

Claims 5 and 39-51 and 53-58 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hassler et al., (1990), Becker et al., (1998), Katzen et al., (1998) and further in view of Feinbaum R (1998) is maintained.

In support of their request that said rejection be withdrawn, applicants' provide the following arguments:

(A) Applicants' note that Hassler's mutant are defective in xanthan biosynthetic pathway, and Hassler specifically shows that acetylation and pyruvylation can affect the viscosmetric properties of xanthan and the claimed invention relates to over-expression of two specific gum genes, namely *gum B* and *gumC*, which over-expression is unrelated to the mutation of biosynthetic pathway of xanthan production. Becker et al., provides discussion of the proposed biosynthetic pathway with hypothesized roles of *gum B* and *gumC* products in polymerization or export of polymer.

(B) Examiner has not explained how the mutations of Hassler et al., when combined with Becker's discussion of potential biosynthetic pathway would lead one of skill to arrive at the over-expression...

(C) Examiner has not provided a nexus between the mutations provided by Hassler and Becker's proposed biosynthetic pathway to arrive at the subject matter of the pending claims.

These arguments are not found to be non-persuasive for the following reasons.

Reply for (A), (B) & (C):

1) At the outset examiner would like to point out that the amended claims are directed to over-expression of *gum B* and *gumC* in a mutant (undefined genetic lesion) of *Xanthomonas campestris* XWCM1 and not the wild-type strain.

2) The cited references indeed provide the teaching, suggestion and motivation for the instant invention i.e., method for the production of xanthans with increased viscosity by selectively increasing the gene product of *gumB* and *gumC*.

i) Becker et al., as previously cited (pages 10-11 of FOAM dated 02/21/2007) with respect to the biochemical assignments for all the genes involved in the xanthan biosynthetic pathway in *Xanthomonas campestris*; specifically the reference teaches a) that gene products of *gumB* and *gumC* are involved in the terminal stages of xanthan biosynthesis and regulate the xanthan export and polymerization of the molecule and b) Becker et al., had envisioned that mutants (not directly involved in the biosynthesis of xanthans) that produced xanthans with increased viscosity as a result of increased pyruvate content can be further improved by overexpressing genes of xanthan biosynthetic pathway (page 149, second paragraph).

ii) Examiner would like to point out that Hassler's reference also provides knowledge regarding mutants not directly involved in the biosynthetic pathway, but enzymes that are involved in adding either acetyl or pyruvate moieties to the mannose residues in the repeating structural units of xanthan polymer, this "decoration" of mannose moieties either with acetyl or pyruvate moieties determines the viscosity of xanthan. Examiner would like to draw the attention of the applicants' to the following mutants described by Hassler et al., in the Introduction section (pages 182-183, Table: 1 and Figure 2), specifically the following mutants: "Mutants were constructed that comprises all possible combinations of mutations in genes F, G and L...Analysis

of the properties of this family of variant xanthans allows investigations of the effect of the individual modifications on polymer properties".

iii) Katzen et al., also provide evidence that inactivation of *gum B* or *gumC* or *gumE* in the wild-type strain was lethal (as these genes are involved in polymerization and export of xanthan). Absence or deficiency of one of the *gum B* or *gumC* or *gumE* would disrupt the polymerization process impairing accumulation of lipid-linked intermediates and elevated levels of these compounds might prove toxic to the cells (page 1615, columns 1-2).

Therefore, all the elements of obviousness i.e., teaching, suggestion and motivation are provided in the cited prior art to skilled artisan. Given the knowledge of biosynthetic pathway for xanthan synthesis, especially involvement of *gumB* (polysaccharide translocation) and *gumC* (degree of polymerization), a skilled artisan would be motivated to increase specifically the *gum B* and *gumC* gene products involved in the terminal stages of xanthan biosynthesis that regulate the xanthan polymerization and export in a strain tailored to produce xanthan with increased viscosity (examiner would also like to emphasize that the *gum B* and *gumC* genes are overexpressed in a mutant of undefined genetic lesion in the instant invention). Said method of producing xanthan polymer preparation having increased viscosity will entail/encompass; increasing the activity of genes involved in the polymerization i.e., *gum B*, as *gum B* is clearly involved in the polymerization of xanthan determining the size and length of the xanthans (as taught by Becker et al.) and also genes involved in the transport of xanthan i.e., *gumC*, as one would like to efficiently transport the xanthan with increased viscosity that accumulates intra-cellularly and potentially detrimental to the engineered microorganism (as taught by Hassler et al. and Katzen et al). Therefore, in engineered cells that produce xanthans with increased

viscosity, to achieve efficient polymerization, secretion and at the same time overcome the intracellular accumulation of xanthans with increased viscosity that could potentially result in toxic effects on the engineered cells, a skilled artisan would be motivated to increase the amount of *gum B* and *gum C* gene products. It is *prima facie* obvious to a skilled artisan to realize the strong nexus provided by the teachings of the prior art and would be motivated to combine the teachings of cited references at the time of the instant invention with high likelihood of success for a method of producing xanthan polymers with high viscosity that involves increasing the amount of *gum B* and *gum C* gene products in engineered cells.

Summary of Pending Issues

The following is a summary of issues pending in the instant application.

1) Claims 5, 39 and 50 are objected to, due to informalities.

2) Claims 5, 39 (40-49 depending therefrom) and 50 (51 and 53-58 depending therefrom) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3) Claims 5 and 39-51 and 53-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement (Biological Deposit).

4) Claims 5 and 39-51 and 53-58 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Hassler et al., (1990), Becker et al., (1998), Katzen et al., (1998) and further in view of Feinbaum R (1998).

Conclusion

Claims 5 and 39-51 and 53-58 are rejected for the reasons identified in the Rejections and Summary sections of this Office Action. Applicants must respond to the rejections in each of the sections in this Office Action to be fully responsive for prosecution.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Final Comments

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ganapathirama Raghu whose telephone number is 571-272-4533. The examiner can normally be reached on 8 am - 5 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and for After Final communications. Any inquiry of a general nature or relating to the status of the application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ganapathirama Raghu, Ph.D.
Patent Examiner
Art Unit 1652
Oct. 08, 2007.